PTO/SB/88 (11-99)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR ACCESS OF ABANDONED APPLICATION UNDER 37 CFR 1.14(a)

RECEIVED
AUG 11 2000
File Information Unit

In re Application of	
Application Number: SN, 08/612061	Filed: Mar, 07, 1996
Group Art Unit: 3306	Examiner: Blevins

Paper No. 11

Assistant Commissioner for Patents
Washington, DC 20231

I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

___ (A) referred to in United States Patent Number 6,059,713, column _____,

___ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. _____, filed _____, on page _____ of paper number _____,

___ (C) an application that claims the benefit of the filing date of an application that is open to public inspection, i.e., Application No. _____, filed _____, or

___ (D) an application in which the applicant has filed an authorization to lay open the complete application to the public.

Please direct any correspondence concerning this request to the following address:

_____

_____

_____

_____ 08/11/2000
Signature Date

SHAHAB GHAYOUR
Typed or printed name

FOR PTO USE ONLY

Approved by: _____ (Initials)

Unit: _____

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

CATHETER SYSTEM HAVING TUBULAR RADIATION SOURCE WITH MOVABLE GUIDE WIRE

CROSS REFERENCES TO CO-PENDING APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 08/984,490, filed Dec. 8, 1997, entitled "Catheter System having Tubular Radiation Source", now abandoned; which is a continuation-in-part of co-pending U.S. patent application Ser. No. 08/812,757, filed Mar. 6, 1997, entitled "Perfusion Balloon Catheter with Radioactive Source", pending the entire disclosures of which are incorporated herein by reference. The present application is also related to co-pending U.S. patent application Ser. No. 08/782,471, filed Jan. 10, 1997, entitled "Intravascular Radiation Delivery System", pending; and to U.S. patent application Ser. No. 08/612,061, filed Mar. 7, 1996, entitled "Perfusion Balloon Angioplasty Catheter", now abandoned, the entire disclosures of which are herein incorporated by reference.

FIELD OF THE INVENTION

The present application is related to medical devices and methods for inhibiting restenosis in blood vessels. Specifically, the present invention is related to intravascular catheters utilizing a tubular member having a distally disposed radiation source over a core wire and methods of their use.

BACKGROUND OF THE INVENTION

Intravascular diseases are commonly treated by relatively non-invasive techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA). These therapeutic techniques are well known in the art and typically involve use of a guide wire and a balloon catheter, possibly in combination with other intravascular devices. A typical balloon catheter has an elongate shaft with a balloon attached proximate to its distal end and a manifold attached to the proximal end. In use, the balloon catheter is advanced over the guide wire such that the balloon is positioned adjacent a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened.

Vascular restrictions that have been dilated do not always remain open. In approximately 30% of the cases, a restriction reappears over a period of months. The mechanism of this restenosis is not fully understood. The mechanism is believed to be different from the mechanism that caused the original stenosis. It is believed that rapid proliferation of vascular smooth muscle cells surrounding the dilated region may be involved. Restenosis may be in part a healing response to the dilation, including the formation of scar tissue.

Intravascular radiation, including thermal, light and radioactive radiation, has been proposed as a means to prevent or reduce the effects of restenosis. For example, U.S. Pat. No. 4,799,479 to Spears suggests that heating a dilated restriction may prevent gradual restenosis at the dilation site. In addition, U.S. Pat. No. 5,417,653 to Sahota et al. suggests that delivering relatively low energy light, following dilatation of a stenosis, may inhibit restenosis. Delivery of radioactive radiation has been proposed as a means to prevent or reduce the effects of restenosis. Dake et al. suggest delivering radiation within the distal portion of a

tubular catheter. Fischell, in the publication EPO 0 593 136 A1, suggests placing a thin wire having a radioactive tip near the site of vessel wall trauma for a limited time to prevent restenosis. Problems exist in attempting to provide uniform radiation exposure using a point or line source. Specifically, as the radiation varies inversely with the square of distance for a point source and inversely with distance for a line, a source laying off center near one vessel wall may significantly overexpose the nearby wall while underexposing the further away wall. This is especially critical for beta radiation which is absorbed by tissue and blood at a relatively short distance from the source.

Use of continuous centering balloons having a beta radiation source within has been suggested, but may allow the radiation source to "warp" when placed across curved vessel regions, allowing the balloon to bend but having the central radiation source lying in a straight line between the two ends.

What remains to be provided is an improved apparatus and method for delivering uniform radiation to vessel interiors to inhibit restenosis.

SUMMARY OF THE INVENTION

The present invention includes a radiation source which can be used to inhibit restenosis of blood vessels, the source having a tubular radioactive distal region adapted to slide over a radiation source guide wire or core wire. In all embodiments, the radiation source guide wire or core wire extends within a lumen that extends over substantially the entire length of a delivery catheter. The core wire further extends out the proximal end of the delivery catheter a sufficient distance or length to thread the tube or radiation source thereon.

One radiation source includes a tubular body having a lumen the entire tube length, which can be used with a radiation source guide wire extending proximally out of the proximal end of a delivery catheter for at least the length of the tube to facilitate exchanges. Another source includes a tubular body having a lumen the entire tube length but having a first guide wire port on its distal end and a second guide wire exit port a short distance proximal of the distal end, allowing the use of a shorter radiation source guide wire extending proximally from the proximal end of the delivery catheter to thread the tube thereon.

Yet another source includes a short radioactive, tubular distal member disposed at the end of a shaft with the short distal tubular member having a distal and proximal opening for threading over the radiation source guide wire, again allowing the use of a radiation source guide wire which extends a short distance proximally out the proximal end of the delivery catheter to thread the tubular radiation source lumen thereon. The tubular body could also be of a two-piece construction with the short distal radiation portion detachable from a long proximal segment.

Still another radiation source features an elongate tubular body having a short distal radioactive portion and a lumen the entire tube length and having a longitudinal slot extending through the tube wall over a portion of the length of the tubular body. The slot extends from the proximal end of the tubular body, where it is open to the lumen at the proximal end, to a point proximate the radioactive portion. The slotted embodiment allows a radiation source guide wire to be threaded by extending the wire radially through the slot, holding the core wire position constant, while advancing the tube into the catheter and patient, thereby threading the entire tube while requiring the core wire to extend proxi-